DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

MAR 29 2001

WARNING LETTER

VIA FEDERAL EXPRESS
VIA FACSIMILE

Mr. Darren Starwynn
President
Microcurrent Research, Incorporated
13444 North 32nd Avenue
Suite 15
Phoenix, Arizona 85032

Re: Acutron Mentor TENS device,
K981976

Dear Mr. Starwynn:

The Office of Compliance (OC), Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA) has reviewed your web site at the Internet address: http://www.microcurrentresearch.com for the Acutron Mentor TENS Device. This product is manufactured by Microcurrent Research, Incorporated (Microcurrent Research) and is a device as defined within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The Acutron Mentor was cleared under section 510(k) of the Act and is intended for the symptomatic relief of chronic intractable pain, post-traumatic pain, and post-surgical pain. Your web site at http://www.microcurrentresearch.com/description.htm makes numerous claims for the Acutron Mentor that have not been cleared by the agency i.e., healing acceleration of muscle and joint problems, muscle mass enhancement, meridian therapy, analgesic nerve block, reducing the need for surgery of the foot, knee, back, and TMJ, fibromyalgia, and Reflex Sympathetic Dystrophy (RSD).

Additionally, your web site at http://www.microcurrentresearch.com/testimonials.htm contains many references and testimonial claims for the Acutron Mentor that have not been cleared by FDA. Testimonial statements made by other individuals but appearing on your web site essentially become the claims of the company. These references and testimonials make claims for the Acutron Mentor that imply a therapeutic benefit resulting from the use of the Acutron and include: facial rejuvenation, Bell's Palsey, relief of headaches, migraines, sinusitis, tonification of the sense organs, greatly improved skin and muscle tone, relief of visceral pain, somatic pain,

phantom pain of amputation, rheumatoid arthritis, edema, contusions and sprains, myofascial pain, shoulder capsulitis, elbow tendonitis, meniscus injuries, non-surgical face lifts, HIV-related peripheral neuropathy, treatment of pre and post-surgical carpal tunnel patients, diabetic extremity skin ulcers, neurogenic urinary bladder incontinence, patients with severe disc injury, sciatica, broken bones and open wounds, and low back or wrist pain. None of these claims have been cleared.

Promoting the Acutron Mentor for the above claims causes this device to be adulterated within the meaning of section 501(f)(1)(B) of the Act in that it is a Class III device under section 513(f), and does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a), or an approved application for investigational device exemption (IDE) under section 520(g).

The Acutron Mentor is also misbranded within the meaning of section 502(o) of the Act, in that a notice or other information respecting the modification in the intended use of the device was not provided to FDA as required by 21 CFR 807.81(a)(3)(ii), and the device was not found to be substantially equivalent to a predicate device.

This letter is not intended to be an all-inclusive list of deficiencies associated with your Acutron Mentor device. It is your responsibility to ensure adherence to each requirement of the Act and Federal regulations. The specific violations noted in this letter may represent practices used in other promotion or advertising materials used by your firm. You are responsible for investigating and reviewing these materials to assure compliance with applicable regulations.

You should take prompt action to correct these violations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office, in writing, within 15 working days of receipt of this letter, outlining the specific steps you have taken to correct the cited violations. Your response should also include all steps being taken to address misleading information currently in the market place and actions to prevent similar violations in the future. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Mr. Steven E. Budabin, Consumer Safety Officer, Promotion and Advertising Policy Staff (HFZ-302), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

A copy of this letter is being sent to FDA's Los Angeles District Office. Please send a copy of your response to the District Director, Food and Drug Administration (HFR-PA200), 19900 MacArthur Boulevard, Suite 300, Irvine, California 92715.

Sincerely yours,

for Larry D. Spears
Acting Director
Office of Compliance
Center for Devices and
Radiological Health